SUBMISSION FORM University System/Employee Intellectual Property Joint Participation MUSP 407

This form is to be submitted with any Board of Regents item whereby a campus seeks the approval of an agreement with or arrangement regarding an employee pursuant to 20-25-109 MCA and Regents Policy 407.

When the submission concerns matters of trade secrets or confidential business information, or any other matter entitled to privacy under state or federal law (e.g., the federal statute known as Bayh/Dole) the submitting campus may request consideration of the submission, in whole or in part, in executive session.

The submitting campus should also provide the Commissioner a copy of the contract(s) that form the basis for the cooperative arrangement for which approval is sought. Submission of the contract does not indicate a conclusion that all or part of the contract is a public document and the question of whether it is in whole or in part protected from public disclosure will be evaluated on a case by case basis.

1. Summarize the nature of the intellectual property that was developed by the employee seeking approval. Indicate the sources of funding for the research that resulted in this invention.

The intellectual property is:

- Deuterated Imidazopyridines (DI). DI's are potent anti-mycobacterial agents with improved metabolic stability. MSU Tech ID: MGC-2018-DEUt.
- Bd Oxidase Inhibitors for the Treatment of Mycobacterial Diseases. MSU Tech ID: MGC-2018-MYCO.

These technologies could potentially be commercialized for treatment of drug resistance strains of diseases like tuberculosis. Funding was awarded by National Institutes of Health and through the company who is licensing the technology, Hsiri. Hsiri is a developmental stage company focused on discovering and developing therapies for infections due to drug resistant bacteria.

- 2.
- a. Name(s) of the university employee(s) involved.
 - Garrett Moraski
 - Co-Inventor of intellectual property
 - Senior Research Scientist in the Department of Chemistry and Biochemistry at Montana State University
 - 4.9% equity interest of developmental stage company Hsiri.

Mr. Moraski has a Conflict of Interest Management Plan that is overseen by the MSU Office of Research Compliance. The purpose of the plan is to accurately describe the potential conflicts in writing, create explicit agreements to protect against actual conflicts and to facilitate oversight. A Plan Manager has been assigned to review the case annually and whenever major changes in circumstance occur. Mr. Moraski's original plan was developed in October of 2103, with the most recent review and update being on the agenda for the Conflict of Interest Committee to review in February of 2019. Because of his financial interests in Hsiri, Mr. Morarski has agreed that he will not participate in any capacity on the MSU side on any sponsored research or contracted work between MSU and Hsiri.

b. Name(s) of business entity(ies) involved.

Hsiri, a development stage company incorporated in Delaware. The business development staff is in Media, Pennsylvania and the discovery laboratories are located in South Bend, Indiana.

- 3. The university and employee(s) are seeking approval for (check as many as appropriate):
 - **a.** \(\sum \) The employee to be awarded equity interest in the business entity
 - **b.** The employee to serve as a member of the board of directors or other governing board of the business entity
 - **c.** \boxtimes The employee to accept employment from the business entity
 - d. Other. The employee to serve as a consultant for the company

4.

a. Summarize the nature of the relationship between the university and the business entity (e.g., the entity is licensing the intellectual property from the university, the entity is co-owning the intellectual property with the university).

DI Agent - MSU Tech ID: MGC-2018-DEUt

- Co-invented and Co-owned with Notre Dame.
- A patent has been filed.
- The agent has been licensed to Hsiri through Notre Dame
- MSU has an interinstitutional agreement with Notre Dame to integrate new DI technology into an existing Notre Dame license to Hsiri.

_

Bd Oxidase Inhibitors – MSU Tech ID: MGC-20180MYCO

- Co-invented and Co-owned with Notre Dame
- A patent has been filed
- MSU has an additional interinstitutional agreement with Notre Dame and Nanyang University (Singapore) on this IP.
- This technology is licensed to Hsiri.

b. The proposed duration of the agreement or arrangement.

The Agreement can be terminated with ninety (90) days notice, otherwise it expires for the following reasons:

- The patent issued on the technology expires.
- If the patent is abandoned by mutual consent of the parties.
- Upon the termination of all COMMERCIAL AGREEMENTS relating to the TECHNOLOGY, whichever event shall last occur.

c. The conditions under which the agreement may be terminated or dissolved.

This Agreement shall expire with the expiration of (a) the last to expire patent issued on the TECHNOLOGY, (b) on abandonment of all patent applications on the TECHNOLOGY, provided such abandonment is by mutual consent or (c) upon the termination of all COMMERCIAL AGREEMENTS relating to the TECHNOLOGY, whichever event shall last occur.

- Any one PARTY may terminate that PARTY'S obligations and benefits under this Agreement by giving ninety (90) days notice to the other PARTIES. However, termination of this Agreement shall not affect Section 7.4 or any COMMERCIAL AGREEMENT entered into prior to the termination date and all applicable provisions of this Agreement shall continue to apply until the term specified in Section 7.1, including without limitation the reimbursement of costs associated with patenting, the distribution of REVENUE, and notification regarding license agreements and patent applications. The terminating PARTY, after providing notice of its intentions, will proceed to meet all obligations, financial or otherwise, to the other PARTIES by the end of the ninety (90) days notice period, including any steps reasonably necessary to perfect legal rights to the TECHNOLOGY in the remaining PARTIES and to enable the remaining PARTIES to properly manage any pending or issued patents.
- If a PARTY elects to terminate in the manner provided in Section 7.2, it shall forfeit all rights to the TECHNOLOGY and to any pending or issued patents (including all rights to use or permit others to use the TECHNOLOGY for any commercial purpose whatsoever), except that such terminating PARTY shall maintain the right to practice the TECHNOLOGY for its own internal non-commercial research, clinical, and educational purposes. However, if the remaining PARTIES subsequently license the INVENTION and receive royalty or other income thereunder, the PARTY having terminated this Agreement shall be entitled to have any unreimbursed patent expenses that were incurred while the Agreement was in force paid from such income, but only after the remaining PARTIES have recovered their expenses in full. After the out-of-pocket patent expenses of the terminating PARTY have been reimbursed in full, that terminating PARTY shall have no further rights whatsoever to any income from any license agreement(s) related to the TECHNOLOGY.
- 7.4 Provisions which survive termination or expiration of this Agreement are those relating to confidentiality, limitation of liability, indemnification, and others which by their nature are intended to survive.
- 5. Explain specifically how the University System or the State of Montana will likely benefit from the agreement or arrangement.
 - a. The IP is jointly owned by MSU and the agreements allow lead to a fully negotiated license with annual fees and royalties that would generate significant revenue upon successful commercial development of the technology. The DI agent technology will bring in royalties to MSU by the end of the year.
 - b. If successful and brought to market, the impact of a medication to treat drug-resistant strains of tuberculosis could be life changing for the over 10 million individuals who have drug resistant tuberculosis. Although currently few Montana residents have drug resistant tuberculosis, There are on average two cases of TB in MT a year, and usually one of the

- cases is drug resistance. For those who do have TB the treatment is costly. In 2016, there was a reported case of active TB on the MSU campus.
- c. MSU would be known as one of the institutions who was able to cultivate a cure for a deadly and costly disease. Every 20 seconds someone dies of TB globally.
- d. Continued collaborative research opportunities for Montana State University and its students. Additionally, there is potential for spin out companies in MT and additional sponsored research at MSU.
- e. MSU would become known as an institute with translational intellectual property, which could foster new licenses from new and existing MSU technology.

6. Summarize the financial terms of the agreement or arrangement. Include:

a. The value, nature and source of the University's contribution.

Since acquiring the IP, Hsiri has re-paid all the patent related costs and will continue to pay the filing and maintenance fees. The net costs to MSU is currently zero.

b. The value and nature of the employee's contribution.

As an employee of MSU, Mr. Moraski will assist in the preparation and completion of the patent filing.

c. The anticipated revenue to be generated by the project and the time line for generating such revenue.

It is difficult to put an anticipated revenue on such a product at this early stage. Currently, MSU receives annual royalties from Notre Dame, and the royalty percentage for BI is in negotiations. Future technologies that are advanced from these compounds will also produce royalties. As Hsiri gets financial investment and these technologies meet milestones there be royalties to the institutions annually.

d. The manner in which revenue and expenses will be shared by the parties.

Royalty revenues will be shared by MSU and the inventor. Further expense information is detailed in the confidential agreement language.

e. The nature of each party's equity interest in the project. If none, so indicate.

Garrett Moraski holds 4.9% equity in Hsiri.